

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Clark et al.	Group Art Unit: 3771
Application No: 09/414,384 Confirmation No: 3236	Examiner: Dixon, Annette Fredricka
Filed: October 7, 1999	Attorney Docket No: NK.0037.00
Title: FLOW RESISTANCE MODULATED AEROSOLIZED ACTIVE AGENT DELIVERY	January 22, 2008 San Francisco, California

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on November 20, 2007, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

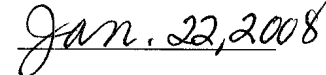
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By:


Leslie Mills

Date:



Status of Claims

Claims 21-36 are presently pending in the case. Claims 1-20 have been cancelled. Claims 21-36 have been finally rejected. The appeal of the rejection of each of claims 21-36 is hereby maintained.

Grounds of Rejection to be Reviewed on Appeal

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 21-36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,655,520 to Howe et al (hereinafter Howe et al).

Argument

Appellant believes each of claims 21-36 are improperly rejected and are therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on August 30, 2007. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on November 20, 2007. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

To summarize Appellant's position, the rejection of independent claim 21 under 35 USC §103(a) as being unpatentable over Howe et al is improper for one of at least two reasons. First, Howe et al does not teach or suggest and the Examiner has failed to account for all features positively set forth in the claims (i.e. the Examiner has failed to establish a prima facie case of obviousness). Secondly, the modification proposed by the Examiner would not have been an obvious one to one of ordinary skill in the art at the time the invention was made.

Regarding the first contention, Howe et al fails to disclose or render obvious a valve that provides a high flow resistance at the onset of a patient's inhalation and that subsequently opens to provide a lower flow resistance. Appellant and Howe et al each describe valves in an aerosolization device, but the valves are very different. In many ways, they are opposites. Appellant's valve is one that starts at a very high flow resistance (sufficiently high that little or no air flows through the device) and then is modulated to a lower flow resistance (see Appellant's Figure 3). This change in flow resistance allows for an increased flow rate through the device (see Appellant's Figure 4). In contradistinction, Howe et al discloses a flow regulator type valve. The objective of the Howe et al valve is to maintain a constant flow rate during an inhalation (see column 4 line 57 to column 5 line 10). Accordingly, the Howe et al valve changes its flow resistance in response to a user's inhalation strength so as to maintain a constant flow rate. Thus, while both valves change their flow resistance, Appellant's valve's flow resistance **decreases** as the inhalation strength is increased relative to the onset of

inhalation and Howe et al's valve's flow resistance **increases** with increasing inhalation strength. It is important to note that the difference between the valves is structural, not functional, in that the valves operate differently by their design.

Despite Appellant's efforts throughout the prosecution of the subject patent application to draft claim language that distinguishes a flow regulator type valve (such as that in Howe et al), the Examiner has repeatedly misconstrued the claim language to allegedly cover the contorted teachings of Howe et al or similar references. The Examiner has maintained this tack in the Examiner's Answer. However, the Examiner's reasoning is flawed, and the Examiner is still not able to make Howe et al's square peg fit into Appellant's round hole.

Specifically, the Examiner tries to demonstrate that Appellant's claim language in claim 21 is sufficiently broad to read on the flow regulator valve of Howe et al, by saying "[u]pon reducing the strength of their (sic) inhalation ... it is clear that the valve [of Howe et al] would open (at least partially) and provide a lower flow resistance thereby allowing a higher flow rate (Column 5, Line 3-5) through the device." This contention by the Examiner is flawed for at least two reasons. First, the contention is based on the premise that inhalation strength can be reduced to a strength less than it is "at the onset of the patient's inhalation" (see language of Appellant's claim 21). Since a patient's inhalation strength at onset of inhalation is zero, there is no way inhalation strength can be reduced to a strength therebelow. Secondly, the Examiner's contention that a lower flow resistance in Howe et al's valve would result in a higher flow rate through the device is simply incorrect. As discussed above and as discussed throughout Howe et al (e.g. see Abstract lines 4-5), the purpose of the Howe et al valve is to maintain a constant flow rate. The Examiner points to column 5 lines 3-5 to support the contention, but those lines support Appellant's contention, not the Examiner's. Because the Examiner's reasoning is flawed in these two ways, the position taken by the Examiner does not demonstrate that Howe et al reads on the language of claim 21.

Undeterred, the Examiner continues on page 6 of the Examiner's Answer with

another attack on the breadth of claim 21. This time, the Examiner considers the "subsequently opens to provide a lower flow resistance..." language of claim 21 to be sufficiently broad to cover a later exhalation by the patient. This reasoning, too, is flawed for at least two reasons. First, the Examiner ignores the positively set forth claim language "wherein the lower flow resistance allows for a higher flow rate through the device." Because there is a flow rate through the device at the "subsequent" time, there is a clear implication that the language refers to the inhalation phase. Secondly, even assuming the "subsequently..." language could properly be read to include a later exhalation, Howe et al would still not read on the language. At the onset of inhalation, Howe et al's flow resistance is at its minimum level (see Figure 3a and column 4 lines 65-67). At no subsequent point, even exhalation, does the valve of Howe et al open more than at the onset of inhalation. In addition, as discussed above, Howe et al's valve maintains a constant flow rate, and therefore the "wherein the lower flow resistance allows for a higher flow rate" limitation is not satisfied by Howe et al.

Furthermore, the Examiner otherwise mischaracterizes the teachings of Howe et al. For example, on page 6 of the Examiner's Answer, the Examiner contends that column 5 lines 17-19 of Howe et al teaches that the flow rate through the Howe et al device need not remain constant. However, a careful reading of the recitation reveals that Howe et al is discussing tailoring the desired flow rate according to each patient (e.g. see column 5 lines 19-22). It is clear when considering the teachings of Howe et al as a whole, that Howe et al is specifically for the purpose of maintaining a constant flow rate during a particular patient's administration of the medicament (e.g. see column 1 lines 10-12).

Concerning the second reason why the obviousness rejection set forth by the Examiner is improper, i.e., that it would not have been obvious to modify the parameters of Howe et al in a manner that would arrive at Appellant's claimed invention as set forth in claim 21, the Examiner again misses the mark. The Examiner is of the position that through routine optimization, Appellant's invention would result. Appellant respectfully disagrees. As discussed in the Appeal Brief, the initial flow resistance in Appellant's

claimed device is sufficiently high to allow little or no flow through the device. If Howe et al were modified as proposed by the Examiner, it would not work. A patient would not be able to generate sufficient flow through the device, and as the Howe et al patient increased his or her inhalation strength, the flow resistance would even further increase. Thus, this is not a situation of simple optimization. Instead, a complete device and valve redesign would be required in order to make Howe et al similar to Appellant's claimed device. And such would be inconsistent with the intended purpose of Howe et al.

For at least these reasons, claim 21 is not properly rejectable under 35 USC §103(a) as being unpatentable over Howe et al. There is no prima facie case established by the Examiner in that aspect of claim 21 are not disclosed or suggested by Howe et al and have not been accounted for by the Examiner. Furthermore, the modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the proposed modification could be applied, with a reasonable likelihood of success, to Howe et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have made the proposed modification in a manner that would result in the invention of claim 21 and there is no evidence to suggest an artisan would have seen the benefit in doing so. Thus, claim 21 is allowable over the references cited.

Independent claims 28 and 32 are also allowable over Howe et al. The distinguishing features of claim 28 and 32 are discussed in the Appeal Brief and need not be further elaborated.

Conclusion


Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: 22 JAN 2008

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